

85

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
25 May 2001 (25.05.2001)

PCT

(10) International Publication Number
WO 01/36470 A3

- (51) International Patent Classification⁷: C07K 14/47, 16/30, G01N 33/574, C12Q 1/68 (72) Inventor: WATKINS, Brynmor: 99 Summer Street, Waltham, MA 02452 (US).
- (21) International Application Number: PCT/US00/31483 (74) Agent: BRODOWSKI, Michael, H.: Testa, Hurwitz & Thibault, LLP, High Street Tower, 125 High Street, Boston, MA 02110 (US).
- (22) International Filing Date: 16 November 2000 (16.11.2000) (81) Designated States (*national*): AU, CA, JP.
- (25) Filing Language: English (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).
- (26) Publication Language: English
- (30) Priority Data:
60/165,673 16 November 1999 (16.11.1999) US
60/172,170 17 December 1999 (17.12.1999) US
60/178,860 27 January 2000 (27.01.2000) US
60/201,721 3 May 2000 (03.05.2000) US
Not furnished 10 November 2000 (10.11.2000) US
- Published:
— with international search report
- (88) Date of publication of the international search report: 24 January 2002
- (71) Applicant: MATRITECH, INC. [US/US]: 300 Nevada Street, Newton, MA 02460 (US).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



WO 01/36470 A3

(54) Title: METHODS AND COMPOSITIONS FOR DETECTION AND TREATMENT OF BREAST CANCER, BASED ON BREAST CANCER-ASSOCIATED POLYPEPTIDES

(57) Abstract: The invention provides a wide range of methods and compositions for detecting and treating breast cancer in an individual. Specifically, the invention provides target breast cancer-associated proteins, which permit a rapid detection, preferably before metastases occur, of breast cancer. The target breast cancer-associated protein may be detected, for example, by reacting the sample with a labeled binding moiety, for example, a labeled antibody capable of binding specifically to the protein. The invention also provides kits useful in the detection of breast cancer in an individual. In addition, the invention provides methods utilizing the breast cancer-associated proteins either as targets for treating breast cancer or as indicators for monitoring the efficacy of such a treatment.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/31483

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 C07K14/47 C07K16/30 G01N33/574 C12Q1/68		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) IPC 7 C07K G01N C12Q		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) MEDLINE, CHEM ABS Data, BIOSIS		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; BAZEL, SHAMIDEH ET AL: "Characterization of purified cathepsin D from malignant, human breast tissue" retrieved from STN Database accession no. 130:334429 CA XP002166729 & INT. J. ONCOL. (1999), 14(2), 315-319, 1999, abstract</p> <p style="text-align: center;">— -/--</p>	1
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents: *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *G* document member of the same patent family		
Date of the actual completion of the international search 18 September 2001		Date of mailing of the international search report 05/10/2001
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016		Authorized officer Masturzo, P

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/31483

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; GIUFFRIDA, MARIA GABRIELLA ET AL: "Isolation and characterization of full and truncated forms of human breast carcinoma protein BA46 from human milk fat globule membranes" retrieved from STN Database accession no. 128:319654 CA XP002166730 & J. PROTEIN CHEM. (1998), 17(2), 143-148, 1998, abstract</p>	1
X	<p>--- DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; ALFONSO, MAURO ET AL: "Two monoclonal antibodies identifying human breast carcinoma associated antigens" retrieved from STN Database accession no. 123:81386 CA XP002166731 & BIOTECNOL. APL. (1994), 11(1), 12-19, 1994, abstract</p>	1
X	<p>--- DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; AUTIERO, MONICA ET AL: "A 17 - kDa CD4-binding glycoprotein present in human seminal plasma and in breast tumor cells" retrieved from STN Database accession no. 123:30958 CA XP002166732 & EUR. J. IMMUNOL. (1995), 25(5), 1461-4, 1995, abstract</p>	1
X	<p>--- DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; ALFONSO, M. ET AL: "Monoclonal antibodies for camal and for cama2 identifying human breast carcinoma associated antigens" retrieved from STN Database accession no. 122:185233 CA XP002166733 & IMMUNOLOGIA (1994), 13(3), 102-4, 1994, abstract</p> <p style="text-align: center;">-/-</p>	1

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/31483

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; DAMSTRUP, LARS ET AL: "Estrogen-regulated proteins in human breast cancer: Clinical value in advanced breast cancer and correlation with estrogen receptor" retrieved from STN Database accession no. 118:188899 CA XP002166734 & RECENT ADV. CELL. MOL. BIOL., WORLD CONGR. C.M.B., 1ST (1992), MEETING DATE 1991, VOLUME 4, 243-51. EDITOR(S): WEGMANN, RAYMOND J.;WEGMANN, MARIA A. PUBLISHER: PEETERS PRESS, LEUVEN, BELG., 1992, abstract</p>	1
X	<p>DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; MORETTI-ROJAS, INES ET AL: "A cDNA for the estradiol-regulated 24K protein: control of mRNA levels i MCF-7 cells" retrieved from STN Database accession no. 109:123471 CA XP002166735 abstract & BREAST CANCER RES. TREAT. (1988), 11(2), 155-63, 1988, abstract</p>	1
X	<p>DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; BORCHERT, G. H. ET AL: "Molecular forms of prostate-specific antigen in the serum of women with benign and malignant breast diseases." retrieved from STN Database accession no. PREV199799809221 XP002166736 & BRITISH JOURNAL OF CANCER, (1997) VOL. 76, NO. 8, PP. 1087-1094., abstract</p>	1

-/--

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/31483

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; CHORVATH, B. (1) ET AL: "Monoclonal antibodies to two adhesive cell surface antigens (CD43 and CD59) with different distribution on hematopoietic and non-hematopoietic tumor cell lines." retrieved from STN Database accession no. PREV199395076141 XP002166737 & NEOPLASMA (BRATISLAVA), (1992) VOL. 39, NO. 6, PP. 325-329.,</p> <p>abstract</p>	1
X	<p>DATABASE MEDLINE 'Online! US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; SLENTZ-KESLER K A ET AL: "Identification and characterization of K12 (SECTM1), a novel human gene that encodes a Golgi-associated protein with transmembrane and secreted isoforms." retrieved from STN Database accession no. 1998149980 XP002166738 & GENOMICS, (1998 FEB 1) 47 (3) 327-40.,</p> <p>abstract</p>	1
X	<p>DATABASE BIOSIS 'Online! BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; TAKEI, YOSHIFUMI ET AL: "Partial purification of immunoreactive basic fibroblast growth factors from sera of patients with breast cancer and investigation of their mitogenic activity toward BALB/c3T3 fibroblasts." retrieved from STN Database accession no. PREV1994974998430 XP002166739 & JOURNAL OF CLINICAL BIOCHEMISTRY AND NUTRITION, (1994) VOL. 17, NO. 1, PP 19-28.,</p> <p>abstract</p>	1

-/--

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/31483

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	C P PAWELETZ ET AL.: "A novel, proteomic approach to monitor carcinogenic disease progression using surface enhance desorption ionization spectroscopy (SELDI) of laser capture microdissection (LCM)-derived cells from cancer tissue" PROC. AM. ASS. FOR CANCER RESEARCH ANNUAL MEETING, vol. 40, March 1999 (1999-03), page 411 XP000993137 abstract	1
P,X	C P PAWELETZ ET AL.: "Rapid protein display profiling of cancer progression directly from human tissue using a protein biochip" DRUG DEVELOPMENT RESEARCH., vol. 49, no. 1, 2000, pages 34-42, XP001001234 NEW YORK, NY, US ISSN: 0272-4391 the whole document	1
T	B WATKINS ET AL.: "Surface enhanced laser desorption-ionization (SELDI) mass spectroscopy in the discovery of serum markers for breast cancer" TUMOR BIOLOGY., vol. 21, no. suppl. 1, September 2000 (2000-09), page 35 XP001001193 XX, XX abstract	1-62
T	B WATKINS ET AL.: "Identification of serum nuclear matrix protein markers of breast cancer using surface enhanced laser desorption-ionization (SELDI) mass spectroscopy" BREAST CANCER RESEARCH AND TREATMENT., vol. 64, no. 1, December 2000 (2000-12), page 98 XP001001191 NIJHOFF, BOSTON., US ISSN: 0167-6806 abstract	1-61
X	WO 98 42725 A (MUSC FOUNDATION FOR RESEARCH DEVELOPMENT) 1 October 1998 (1998-10-01) page 16, line 32 - line 35	1
X	EP 0 460 607 A (BRISTOL-MYERS SQUIBB CO.) 11 December 1991 (1991-12-11) claim 27	1

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 34-40 and 43-62 (at least partially) are directed to a diagnostic method practised on the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition. Although claims 25-26 and 32-33 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box I.2

Claims Nos.: 1-62

Due to the very generic characterization of the claimed product, which involves unclarity of the whole subject matter of the present application, the search has been performed generally on the breast cancer antigen with molecular weights corresponding to those claimed in claim 1 and dependent products and methods.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/31483

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5561222	A	01-10-1996	US	5866680 A	02-02-1999
WO 9842725	A	01-10-1998	AU	6768598 A	20-10-1998
			EP	1007535 A1	14-06-2000
			WO	9842725 A1	01-10-1998
EP 460607	A	11-12-1991	CA	2043951 A1	06-12-1991
			EP	0460607 A2	11-12-1991
			JP	6169791 A	21-06-1994
			US	5411884 A	02-05-1995